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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/601,971	08/09/2000	Thomas William Rademacher	1012-100US	5898

7590 05/20/2002
Jonathan Alan Quine
Law Offices Of Jonathan Alan Quine
PO Box 458
Alameda, CA 94501

EXAMINER

DECLoux, AMY M

ART UNIT	PAPER NUMBER
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1644

DATE MAILED: 05/20/2002

9

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/601,971

Applicant(s)
Rademacher et al.

Examiner
DeCloux, Amy

Art Unit
1644



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on Feb 28, 2002

2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) 1-23 is/are pending in the application

4a) Of the above, claim(s) _____ is/are withdrawn from consideration

5) ☐ Claim(s) _____ is/are allowed.

6) ☐ Claim(s) _____ is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☒ Claims 1-23 are subject to restriction and/or election requirements.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☒ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.

2. ☐ Certified copies of the priority documents have been received in Application No. _____.

3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)

4) ☐ Interview Summary (PTO-413) Paper No(s). _____

2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

5) ☐ Notice of Informal Patent Application (PTO-152)

3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____

6) ☐ Other: _____

DETAILED ACTION

Applicant's election of Group II with extreme traverse, filed 2-28-02 (Paper No.8) is acknowledged. In view of applicant's remarks, a revised restriction requirement is set forth. As set forth in the MPEP interviews are granted after the first office action. Therefore, Applicant's request for an interview is denied. Applicant has the option of petitioning the restriction requirement.

Please Note: In an effort to enhance communication with our customers and reduce processing time, Group 1640 is running a Fax Response Pilot for Written Restriction Requirements. A dedicated Fax machine is in place to receive your responses. The Fax number is 703-308-4315. A Fax cover sheet is attached to this Office Action for your convenience. We encourage your participation in this Pilot Program. If you have any questions or suggestions, please contact Paula Hutzell, Supervisory Patent Examiner at paula.hutzell@uspto.gov or 703-308-4310. Thank you in advance for allowing us to enhance our customer service. Please limit the use of this dedicated Fax number to responses to Written Restrictions.

1. Applicant's submission of the instant application as a 371 is acknowledged, however Claim 1 does not provide a technical feature that is distinguished over the prior art, as evidenced by Rademacher et al. (Brazil. J. Of Med. And Biol. Res. (1994), Volume 27, pages 327-341) (IDS "D"), who teach a pharmaceutical composition of antibodies against serum GPI-PLD that have been shown to block IgE-stimulated histamine release in rats mast cells, which is IPG dependent, (see entire article including page 334, first paragraph). Therefore, the instant invention lacks Unity of Invention. (It is noted that the inventive entity is not identical to the authorship of said paper because there are additional authors absent in the inventive entity).

2. Restriction is required under 35 U.S.C. 121 and 372. This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. In accordance with 37 CFR 1.499, applicant is required, in response to this action, to elect a single invention to which the claims must be restricted. A restriction is required under 35 U.S.C. 121 and 372 between one of the following groups:

Group I: Claims 1-9 and 15-20, drawn to the embodiment of a method for making a composition for the treatment of a condition mediated by the release of IPGs comprising an antagonist, wherein said antagonist is a substance which is capable of inhibiting release of the IPGs by inhibiting the enzyme GPI-PLD, and drawn to the embodiment of a method for making a composition for the treatment of a condition mediated by the release of IPGs comprising an antagonist, wherein said antagonist is a

substance which is capable of specifically binding to the IPGs and inhibiting the release of histamine caused by the IPGs, and drawn to the embodiment of a method for making a composition for the treatment of a condition mediated by the release of IPGs comprising an antagonist, wherein said antagonist is a substance which is capable of competing with IPGs released from mast cells, basophils or eosinophils but does not cause allergic stimulation of these cell types,

Group II: Claims 11-14, drawn to the embodiment of a method of screening for antagonists of an IPG and said antagonist ,

Group III: Claims 21-23, drawn to a method of treating a condition mediated by the release of IPGs from mast cells, basophils or eosinophils comprising treating with an effective amount of an IPG antagonist, or

Group IV: Claim 10, drawn to the embodiment of an IPG.

3. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

4. If Group I is elected, applicant is required:

A) To elect a method comprising a **specific type of antagonist**, such as an antagonist that comprises an anti-IPG antibody, or a substance capable of inhibiting IPG release in mast cells, basophils or eosinophils, or a substance capable of preventing IPG release in mast cells, basophils or eosinophils, or an inhibitor of the enzyme GPI-PLD, or an antibody capable of inhibiting IPG release by inhibiting cleavage of the IPGs caused by the enzyme GPI-PLD, or a competitive antagonist of the IPGs released from mast cells or basophils or eosinophils, or an antagonist that is a substance which is capable of specifically binding to the IPGs and inhibiting the release of histamine caused by the IPGs, or a substance which is capable of competing with IPGs released from mast cells, basophils or eosinophils but does not cause allergic stimulation of these cell types, all of which are recited in claims 1 or 20.

Regardless of which species is elected, the election of a specific **sub-species of a specific antagonist**, encompassed by the elected species is required, such as a specific IPG obtainable from a specific tissue or cell from a specific species of a living organism.

B) To elect a method comprising a **specific cell**, such as mast cell, basophil or eosinophil,

C) To elect a method comprising a **specific condition or disorder**, such as one recited in claim 2,

D) To elect a method comprising a **specific allergy**, such as one recited

in claim 15.

5. If Group II is elected, applicant is required:

A) To elect a method comprising a **specific cell**, such as mast cell, basophil or eosinophil, as recited in claim 11

B) To elect a method comprising a **specific evaluation**, such as a response to an IPG or release of IPG, as recited in claim 11,

C) To elect a method comprising a **specific assay** such as one recited in claim 13,

6. If Group III is elected, applicant is required:

A) To elect a method comprising a **specific type of antagonist**, such as an antagonist that comprises an anti-IPG antibody, or a substance capable of inhibiting IPG release in mast cells, basophils or eosinophils, or a substance capable of preventing IPG release in mast cells, basophils or eosinophils, or an inhibitor of the enzyme GPI-PLD, or an antibody capable of inhibiting IPG release by inhibiting cleavage of the IPGs caused by the enzyme GPI-PLD, or a competitive antagonist of the IPGs released from mast cells or basophils or eosinophils, as recited in claim 22

B) To elect a method comprising a **specific cell**, such as mast cell, basophil or eosinophil,

C) To elect a method comprising a **specific condition or disorder or allergy**, such as one recited in claim 23. If the disorder characterized by cell infiltration is elected, applicant is required to elect a **specific sub-species** such as a specific cells such as a mast cell or a basophil or an eosinophil, or one specific cell within one cell lineage, as recited in lines 4-5 of claim 23.

7. Applicant is required, in response to this action, to elect a specific species to which the claims shall be restricted if no generic claim is finally held to be allowable. The response must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

8. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

9. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over

the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.

10. Claims 1-23 are generic.

11. The species are distinct each from the other because the encompassed products differ with respect to their physicochemical properties, and the encompassed conditions differ with respect to their etiology, and therefore the species do not have the same corresponding technical feature.

12. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

13. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy DeCloux whose telephone number is (703) 306-5821. The examiner can normally be reached Monday through Friday from 9:00 am to 6:00 pm. a message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

15. Papers **other than elections** related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

Amy DeCloux, Ph.D.
Patent Examiner
Group 1640, Technology Center 1600
May 20, 2002

Amy DeCloux
5-20-02